

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the forgoing amendments and in view of the reasons that follow:

**I. Status of Claims**

1. Claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 37, 40, 43, 51, 54 and 205 - 217 are pending in the application.
2. Claim 1 has been rewritten to incorporate the subject matter of claim 51. No new matter has been added by this amendment.
3. Claim 43 has been rewritten to incorporate the subject matter of claim 1. No new matter has been added by this amendment.
4. Claim 206 has been rewritten to incorporate the subject matter of claim 1. No new matter has been added by this amendment.
5. New claim 218 has been added. New claim 218 incorporates the subject matter of former claim 206. No new matter has been added by this new claim.
6. Claim 51 has been cancelled without waiver or prejudice.
7. Applicants' reserve their right to pursue the subject matter of any cancelled claims in one or more divisional or continuing applications.
8. Following the above noted amendments claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 37, 40, 43, 54 and 205 - 218 are pending in the application.

**II. Oath & Declaration**

9. A new Oath & Declaration is filed concurrently herewith.

**III. Claim Rejections – 35 USC § 112**

10. Claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 37, 40, 43, 51, 54 and 205-217 were rejected under 35 USC § 112 on the basis that the specification does not

reasonably provide enablement for a process using anion exchange chromatography with any protein growth hormone antagonist. Applicants respectfully traverse this rejection.

11. Applicants acknowledge the statement of the Examiner that the specification is enabling for a process for decreasing a level of aggregate of pegylated protein isoforms by anion exchange chromatography using an anion exchange resin under sufficient conditions to decrease said level of such aggregate, wherein the protein is selected from the group consisting of human growth hormone antagonist comprising B-2036 amino acid sequence, pegylated isoforms of B-2036 identified as PEG-1, PEG-2, PEG-3, PEG-4, PEG-5, PEG-6, PEG-7, PEG-8 PEG-9, trisulfide impurity of B-2036 and des-phe impurity of B-2036.

12. Applicants submit that the terms "pegulated protein" and "pegulated protein isoforms" as defined in Applicants' published patent application, Pub. No.: US 2005/0085631, at paragraphs [0075] and [0078] respectively, clearly set forth representative proteins that one of skill in the art could reasonably test to determine whether or not the claimed method achieved the decrease in the level of aggregate as set forth in the claims. The enablement test as noted by the Examiner in *In re Wands*, 8 USPQ2d. 1400, 1404 (Fed. Cir., 1998) permits experimentation so long as it is not undue, see page 1404. It is submitted that the testing of other pegylated proteins by the claimed method would not constitute undue experimentation.

13. Further, the specification itself need not necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art.

14. Applicants request reconsideration of claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 40, 43, 54 and 205-217 and the withdrawal of the rejection under 35 U.S.C. § 112.

#### **IV. Claim Objections**

15. Claims 43, 51, 206, 207 and 209-215 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

16. Claim 1 has been rewritten to incorporate the subject matter of claim 51. Claim 51 was previously written to be dependent only on claim 1. No new matter has been added by this amendment.

17. Claim 43 has been rewritten to incorporate the subject matter of claim 1. Claim 43 was previously written to be dependent only on claim 1. No new matter has been added by this amendment.

18. Claim 206 has been rewritten to incorporate the subject matter of claim 51. Claim 206 was previously written to be dependent only on claim 1. No new matter has been added by this amendment.

19. In regard to claims 207 and 209-215, claim 207 is written to be dependent on rewritten claim 206; claim 209 is written to be dependent on claim 208 which is dependent on rewritten claim 1; claim 210 is written to be dependent on claim 209 and claims 211-215 are written to be dependent on claim 54, which is dependent on rewritten claim 1.

20. Applicants request reconsideration of claims 1, 43, 206, 207 and 209-215 and the withdrawal of the objection to these claims.

#### **V. Conclusion**

21. Applicants respectfully submit that all the grounds for rejection of the pending claims have now been overcome and all the claims are in a condition for allowance.

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22. In the event that the Examiner wishes to discuss any aspect of this response for purposes of advancing the prosecution, please contact the undersigned attorney at the telephone number provided below.

Respectfully submitted,

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